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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LAU, JONATHAN S

ART UNIT

PAPER NUMBER

1623

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,939	Applicant(s) OKAMOTO ET AL.	
	Examiner Jonathan S. Lau	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 Dec 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-13 and 15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 22 Dec 2008, in which claim 1 is amended to change the scope and breadth of the claim; claims 3 and 14 are canceled; and claims 4-11 are amended to correct minor informalities.

This application is the national stage entry of PCT/JP04/05760, filed 22 Apr 2004; and claims benefit of foreign priority document JAPAN 2003-119710, filed 24 Apr 2003. Currently an English language translation of this foreign priority document has not been made of the record.

Claims 1-2, 4-13 and 15 are pending in the current application. Claim 15, drawn to a non-elected invention, is withdrawn. Claims 5 and 7-11, drawn to non-elected species, are **rejoined**. Claims 1, 2 and 4-13 are examined on the merits herein.

Election/Restrictions

The Election of Species requirement detailed in the Office Action mailed 08 May 2008 is withdrawn.

Claims 5 and 7-11, previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, are **rejoined** and examined on the merits herein.

Rejections Withdrawn

Applicant's Amendment, filed 22 Dec 2008, with respect to claims 1, 2, 12 and 13 rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement has been fully considered and is persuasive, as amended claim 1 does not recite the phrase "a substituted or unsubstituted aromatic group".

This rejection has been **withdrawn**.

Applicant's Remarks, filed 22 Dec 2008, with respect to claims 1-4, 6, 12 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Acemoglu et al. (Chirality, 1998, 10, p294–306, of record) in view of Okamoto et al. (Bull. Chem. Soc. Jpn. 1990, 63, 955-957, of record) has been fully considered and is persuasive, as Applicant's Remarks are persuasive regarding Acemoglu et al. in view of Okamoto et al. failing to teach any equivalence between the carbonyl functional group, a carbamate functional group, and general formula (I) of the instant invention. Therefore a polysaccharide substituted with a group represented by general formula (I) of the instant invention would not have been obvious to one of ordinary skill in that art by the combination of Acemoglu et al. in view of Okamoto et al.

This rejection has been **withdrawn**.

The following are new grounds of rejection.

Claim Rejections - 35 USC § 112

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds having the general formula (I) such as formulas IV-VII in claims 5-8 and general formula (I) wherein R is represented by formula VIII-X in claims 9-11, does not reasonably provide enablement for any compound having the general formula (II) or for all species of R according to general formula (III) in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A separating agent for enantiomeric isomers comprising, as an active ingredient, a polysaccharide derivative having at least part of hydrogen

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atoms of hydroxyl groups of a polysaccharide substituted by at least one of atomic groups represented by the following general formulae (I) and (II).

The state of the prior art: The closest prior art, Okamoto et al. (Bull. Chem. Soc. Jpn. 1990, 63, 955-957, of record), teaches phenylcarbamates of a polysaccharide for separating enantiomers, wherein the phenyl group is connected by the structurally distinct carbamate moiety and said phenyl group is substituted at positions 3 and 5 with CF₃, Cl, F, and CH₃ groups (page 955 at bottom of page).

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: While the reactivity of a single chemical functionality in isolation is relatively predictable, the sheer number of possible combinations of possible functional groups on the aryl ring of general formula (III) means that one skilled in the art cannot predict the usefulness for all possible specific combinations of different functional groups. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims is infinite. Any possible chemical structure could potentially be used as the group R according to general formula (III). No limitation is recited on the size of the alkyl, alkoxy, or the alkylthio group. The claimed group R according to general formula (III) encompasses a pentabrominated phenyl ring, and it is unclear what five bulky electronegative substituents will have on the reactivity of the phenyl group. The claimed group R according to general formula (III) encompasses a phenyl ring with 5 nitro groups, and it

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is unclear how a penta-nitro phenyl group may react as it is well known that tri-nitro phenyl groups such as tri-nitrotoluene (ie. TNT) and picric acid are explosively reactive.

Note that while claims 5-8 recite formulas IV-VII indicated as enabled, claims 5-8 encompass compounds having the general formula (II) because claims 5-8 do not require said atomic group to be represented by the general formula (I).

The amount of direction or guidance presented: The specification speaks generally about substituted phenyl rings at page 7. It is suggested that hydrogen, halogen, and alkyl groups are preferred. However, guidance is not given for the size of the alkyl, alkoxy, or the alkylthio group or any limitation on the number of substituents other than hydrogen present.

The presence or absence of working examples: The only working examples provided are for the synthesis of compounds having the general formula (I) and the specific group R having substituents such as 4-methyl, 4-chloro and 3,5-dimethyl in examples 1-7 at pages 14-15.

No working example is provided for the synthesis of a compound having the general formula (II).

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as organic synthetic methods of compounds that are structurally distinct from what is known in the art. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible compounds beyond those known in the art, (such as

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the specific group R such as phenyl or a phenyl group having substituents such as 4-methyl, 4-chloro and 3,5-dimethyl; or the homologous group cyclohexane, bicycloheptane or naphthalene) one skilled in the art would undertake a novel and extensive research program into organic synthetic methods. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of reagents and reaction conditions, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, states that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for any possible compound having the general formula (II) or for all possible species of R according to general formula (III) in claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-8 recite "wherein the atomic group represented by general formula (I) comprises an atomic group represented by the following formula..." (emphasis added). The open transitional phrase "comprises" renders claims 5-8 indefinite because it is

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unclear what other components are present in the atomic group in addition to said following formula. The use of a closed transitional phrase such as "is" or "consists of" would resolve this indefiniteness.

Claims 9-11 recites the limitation formula VIII-X. There is insufficient antecedent basis for this limitation in the claim, as amended claim 1 required R to be according to general formula (III) in claim 1. It appears that the formulas VIII-X are not encompassed by the monocyclic aromatic ring of general formula (III) in claim 1.

Conclusion

No claim is currently in condition for allowance.

This Office Action details new grounds of rejection not necessitated by Applicant's Amendment. Accordingly, this Office Action is made Non-Final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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